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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,025	10/10/2001	Geert Maertens	2752-56	7266

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EXAMINER

LI, BAO Q

ART UNIT PAPER NUMBER

1648

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	<b>Application No.</b> 09/973,025	<b>Applicant(s)</b> MAERTENS ET AL.	
	<b>Examiner</b> Bao Qun Li	<b>Art Unit</b> 1648	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 17 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires three months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.

Claim(s) objected to: None.

Claim(s) rejected: 100-118.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10/10/2001.
10. ☐ Other: \_\_\_\_\_

Bao Qun Li

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### **Advisory Action**

The response to the final action filed on March 17, 2004 under 37 CFR 1.116 has been entered. However, the amendments of the claims and specification have been considered but is not deemed to place the application in condition for allowance.

For purpose of appeal, the status of the claims is as follows:

**Allowed claim(s): NONE.**

**Rejected claim (s): 100-118.**

**Claim(s) objected to: NONE.**

### ***IDS***

The request of IDS filed on September 09, 2003 as originally filed on October 10<sup>th</sup> 2001, has been considered.

### ***Biological Deposit Issue***

Regarding to claim 114, the recipients of biological deposits under the Budapest Treaty have been noticed and accepted by the Office. However, Applicants are still required to provide an assurance in that applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Moreover, the original deposits for monoclonal antibodies 16A6E7 and 12D11F1 are made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

Therefore, claim 114, is still not in condition for allowance.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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2. Claims 100-104, 107-112 and 116-117 are still rejected under 35 U.S.C. 102(a) as being anticipated by Mehta et al. (Patent No. 5,308,750A) on the same ground as stated in the previous Office Action.

3. Applicants traverse the rejection and submitted that One of ordinary skill in the art would appreciate that Example 6 of Mehta describes a procedure for epitope mapping for the antibodies generated against the peptide of SEQ ID NO:6 (aa 643-683). Moreover, column 11, lines 38-44 of Mehta describes SEQ ID NO:6 of Mehta as the immunogen for the generation of monoclonal antibodies to HCV NSI. Further, Table 2 of Mehta (column 16) shows that monoclonal antibodies H13C1 13 and H23C163 have been identified and further tested. Table 2 of Mehta also shows that SEQ ID NO:3 (aa 643-663) and SEQ ID NO:4 (aa 666-683), have been separately used for epitope mapping of these antibodies. The clear conclusion which can be drawn by one of ordinary skill in the art is that monoclonal antibodies H13C1 13 and H23C163 of Mehta specifically reacted with SEQ ID NO:10 (aa 649-655) of the HCV genome. Therefore, the applicants respectfully submit that Mehta only discloses two antibodies and that the epitope for these antibodies consist of amino acids in the range 649-655. The Examiner's assertion that Mehta teaches an antibody which binds to the region of amino acids 666-683 or 671-691 is believed to be an incorrect interpretation and further explanation and clarification is requested.

4. Applicants' argument has been fully considered; however, it is not found persuasive because Mehta et al. disclose several isolated antibodies including the peptide generated monoclonal antibodies H13C1 13 and H23C163 specifically reacted with SEQ ID NO:10 (aa 649-655) and other primary antibodies from the sera of HCV infected patients that reacts with four immunogenic domains including amino acids 607-627 (SEQ ID NO: 2), 643-663 (SEQ ID NO: 3), 666-683 (SEQ ID NO: 4), 671-691 (SEQ ID NO: 5) (lines 267-45 on col. 11) and 643-683 (SEQ ID NO: 6). The binding domains of 666-683 and 671-691 are within the rang of amino acids 655-809. Therefore, the rejection is still maintained.

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5. Claims 112 and 115 are not in the condition for allowance because they depend on the rejected claim 100.

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***Conclusion***

No claims are allowed.

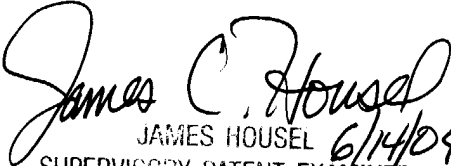
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

June 6<sup>th</sup>, 2004

  
JAMES HOUSEL 6/14/04  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600